

**DETAILED ACTION**

Claims 1-25 are pending.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 and 13-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because the claims are internally inconsistent. The claims set forth both a "single phase" composition and a "nanosized structures", which are particulate structures further defined as having "cubic-like nanosize symmetry". It is unclear how a materials that has measurable structures as "nanosized structures" can be of a single phase. It is unclear how a said "nanosized structures" comprising materials that include a aqueous phase as water and optionally further solubilized ingredients (e.g., claim 16) can both have a measurable size and comprise a single phase.

To the extent applicants intend a "single liquid crystalline phase" (e.g., Q<sub>L</sub>), the do not restrict the claims to either a single LC phase or to a Q<sub>L</sub> phase.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-6, 8-9, 11 and 13-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch et al, US PGPUB 2002/0153508 A1.

Lynch et al discloses ternary systems comprising: (I) water as solvent (paragraph [0067]), (II) alcohol as a hydrotropic agent (paragraph [0045]-[0048]), (III) a fatty acid or ester of a fatty acid including glycerol monooleate as an amphiphilic substance or surfactant (paragraph [0059]-[0067]). The hydrotrope (paragraph [0045] et seq) enable the formation of the cubic phase in the isotropic liquid. The claims read on the materials disclosed in the Lynch et al reference (Table E1 and examples 1, 3 and 4).

Lynch et al (paragraph [0128] et seq) discloses pharmaceutical, cosmetic and agricultural ingredients may be incorporated in the compositions in place of the part of (A), the hydrotrope and the active ingredients may be (paragraph [0129]) water soluble or oil soluble.

Claims 17 and 18 are included herein because the claims 17 and 18 limit either said hydrophobic substance or the hydrophilic substance but each claim reads on the full scope of the undefined said hydrophobic substance or the hydrophilic substance and Lynch et al broadly contemplates both.

Lynch et al differs from the claims in the exemplified weight ratios as claimed (*i.e.*, the weight ratio of (i):(iii) is 5:4 and the weight ratio of (ii):(iii) is 1:4) and the characterization as a “single phase stable, non-viscous and clear nano-sized structures having cubic-like nanosized symmetry”.

Lynch et al discloses ternary compositions for the same utilities as the instant invention. Lynch et al further discloses ternary compositions comprising the same ternary components as the instant invention and broadly disclose said ternary components in the concentrations claimed having a cubic-like structure.

Lynch et al (paragraph [0125]) teaches the gel particles of isotropic liquids have nanometer size of 10 to 500 nanometers. Isotropic liquids have the appearance of a solution (*e.g.*, single-phase) but are often are not single-phase. They merely have the appearance of a single-phase to the naked eye.

Lynch et al discloses dispersions, which would have been expected to generally have a viscosity similar to the continuous phase that disperses the gel particles, *i.e.*, aqueous solution.

Claims 8 and 14 are implicit for the compositions of Lynch et al since Lynch et al (abstract) clearly discloses the gel particles are dispersible to form a dispersion.

See also MPEP 2144.05(I) wherein it sets forth, “*A prima facie case of*

obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985)."

6. Claims 7, 12 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch et al, US PGPUB 2002/0153508 A1, in view of Vatter et al, US 6,528,071.

Lynch et al discloses compositions as set forth in the above anticipation rejection, which the citations and reasoning are herein incorporated by reference.

Lynch et al differs from claims 7 and 12 in the use of a ketone rather than the alcohol.

Lynch et al in (paragraph [0128] and [0129]) discloses the pharmaceutical, cosmetic and agricultural ingredients may take the place of the part of (A), the hydrotrope. Lynch et al ([0129]) further teaches the active ingredients may be water soluble or oil soluble.

Vatter et al discloses carriers for vitamins among other ingredient. Vatter et al (claims 12 and 13) disclose the compositions can take the form of cubic phase liquid crystals. Vatter et al (column 12, lines 54 et seq) disclose flavor oils are may be incorporated into the delivery compositions and typically comprise mixtures including ketones.

These references are combinable because they teach active ingredient delivery compositions that may be cubic phase liquid crystals. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ flavor oils

having ketones as an active ingredient in the compositions of Lynch et al for part of or all of the part of (A), the hydrotrope.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch et al, US PGPUB 2002/0153508 A1, in view of Spicer et al, PGPUB 2002/0160040 A1.

Lynch et al discloses compositions as set forth in the above obviousness rejection, which the citations and reasoning are herein incorporated by reference.

Lynch et al differs from claims 10 in the use of a ketone rather than the alcohol.

Lynch et al in (paragraph [0128] and [0129]) discloses the pharmaceutical, cosmetic and agricultural ingredients may take the place of the part of (A), the hydrotrope. Lynch et al ([0129]) further teaches the active ingredients may be water soluble or oil soluble.

Spicer et al discloses cubic phase liquid crystals as carriers. Spicer et al (paragraph [0061]) discloses incorporating materials encapsulating for compositions that can spontaneously form cubic phase liquid crystals upon hydration including casein.

These references are combinable because they teach active ingredient delivery compositions that may be cubic phase liquid crystals. It would have been obvious to one of ordinary skilled in the art at the time of applicants' invention to employ encapsulating materials in the compositions of Lynch et al for the advantages taught in the Spicer et al reference.

***Response to Arguments***

8. Applicant's arguments filed 05 January 2010 have been fully considered but they are not persuasive.

Applicants (pages 13-17) assert the Lynch et al reference discloses an additional phase and the claims are directed to a single-phase composition. This has been addressed in the rejection above. See also rejection under 35 USC 112, second paragraph. The claims do not limit the system to a "single liquid crystalline phase" (e.g., Q<sub>L</sub>), or to the Q<sub>L</sub> phase.

Furthermore, applicants' claims employ open transitional language, which would not exclude other LC phases.

Applicants' arguments are not deemed to be commensurate in scope with the claims. Further, Applicants have not shown that the scope of the claims only result in forming the alleged LC phase. Applicants' arguments have not been deemed persuasive.

9. Applicants' (pages 18-19) assertions that a proper *prima facie* case has not been presented for claims 7, 12 and 25 because none of the references disclose or suggest the claim limitations. This has not been deemed persuasive because applicants are believed to be reading limitations into the claims. These issues have been addressed in the rejections herein above and the preceding paragraphs regarding the Lynch et al reference.

10. Applicants (page 20) incorrectly state that claim 10 differs in the use of a "ketone" rather than an "alcohol". Point of fact, claim 10 is dependent on claims 9, 8 and 1.

None of claims 10, 9, 8, or 1 are limited to the use of a "ketone" rather than an "alcohol".

Spicer et al (paragraph [0061]) discloses incorporating materials encapsulating for compositions that can spontaneously form cubic phase liquid crystals upon hydration including casein (limitation of instant claim 10).

The remaining arguments have been addressed in the rejection and/or herein above.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel S. Metzmaier whose telephone number is (571) 272-1089. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David W. Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Daniel S. Metzmaier/  
Primary Examiner, Art Unit 1796**

DSM